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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/780,035	GHAYER ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-12 and 14-61* is/are pending in the application.

4a) Of the above claim(s) *39-43 and 47-60* is/are withdrawn from consideration.

5)☒ Claim(s) *37 and 38* is/are allowed.

6)☒ Claim(s) *5-12,14-36,44-46 and 61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Art Unit location and the examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1644.

2. Applicant's amendment, filed 12/12/05, has been entered.
Claims 6-10, 16-21 have been amended.
Claim 4 has been canceled. Claims 1-3 and 13 have been canceled previously.

Claims 5-12 and 14-61 are pending.

Claims 5- 12, 14-38, 44-46 and 61 are under consideration in the instant application.

Claims 39-43, and 47-60 have been withdrawn as being drawn to the non-elected invention.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Action will be in response to applicant's amendments/arguments, filed 12/12/05.
The rejections of record can be found in the previous Office Actions.

Applicant's arguments and the examiner's rebuttal are essentially the same of record.

See the previous Office Actions for a more detailed analysis of applicant's arguments.

3. This is a written description / new matter rejection.

Claims 22, 29, 36 and their dependent claims 23-28, 32-35 and 44-46 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the previous Office Actions.

Applicant's arguments, filed 12/12/05, have been fully considered, but is not deemed persuasive for reasons below.

Applicant's arguments and the examiner's rebuttal are essentially the same of record and as addressed herein.

Applicant relies upon page 12, paragraph 1 of the instant specification for the disclosure of examples of "antigen-binding portions" as well as the disclosure of Ward et al. (Nature 341: 544-546, 1989) for the proposition that antigen binding fragments with two heavy or two light chains were well known in the art.

However, as pointed out previously, the claims, as written, encompass antibodies variable regions both from a L chain, or a H chain, which scope is different from that described in the specification, and therefore is not supported by the specification.

Obviousness is not the standard for the addition new limitations to the disclosure as filed.

It is noted that entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977).

Applicant's reliance on generic disclosure and possibly a single or limited species do/does not provide sufficient direction and guidance to the "features" currently claimed. It is noted that a generic or a sub-generic disclosure cannot support a species unless the species is specifically described. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05.

Applicant is claiming a subgenus not supported by the specification as-filed.

The specification as filed does not provide sufficient written description for this "limitation". The specification does not provide sufficient blazemarks encompassing the above-mentioned "limitation" as currently recited. The instant claims now recite a "limitation" which was not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action.

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP 714.02 and 2163.06.

Again, as pointed out previously, applicant is invited to consider amending the claims to recite language such as "comprising one variable region from L chain, and one variable region from H chain" to obviate this rejection, provided there is sufficient written description in the specification as filed.

Again, applicant appears to be arguing limitations not claimed.

Applicant's arguments are not found persuasive.

4. It appears that in the Section under Claim rejections under 35 USC 12, first paragraph on page 13-14 of applicant's Remarks, filed 12/12/05, that applicant has set forth their arguments as it reads on both enablement and written description.

5. This is a written description (but not a new matter rejection).

Claims 22-36 and 44-46 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the previous Office Actions.

Applicant's arguments, filed 12/12/05, have been fully considered, but are not deemed persuasive for reasons below.

Applicant's arguments and the examiner's rebuttal are essentially the same of record and as addressed herein.

Again, applicant argues that independent claims 22, 29 and 36 comprises "at least two variable regions", that as were well known in the art, and were defined in the specification, each variable region is comprised of three CDRs, that claims 25-36 further specify the amino acid sequences in the variable regions, and that one skilled in the art would recognize that applicants, at the time of filing, were in possession of the claimed invention and the specification as filed fully enable one skilled in the art.

Again as pointed out previously, this argument is not persuasive because with the exception of claims 37 and 38, the amino acid sequences recited in the claims (claims 30 and 31, for example) merely represent a small portion (11 or 17 amino acids in length), but not three CDRs of a light or a heavy chain. As such, even though the claims encompass two variable regions or six CDRs by reciting "a light chain variable region and a heavy chain variable region", the sequence structure of at least two variable regions of one antibody chain is not defined. Therefore, a skilled artisan cannot envision the detailed chemical structure of the encompassed antibody or an antigen-binding portion thereof comprising SEQ ID NO:15 and 16 (or 17), and would not be able to make said antibody or an portion thereof capable of binding human IL-18.

Again, as pointed out previously, applicant is invited to consider amending the claims to recite language such as "comprising one variable region from L chain, and one variable region from H chain" to obviate this rejection, provided there is sufficient written description in the specification as filed.

Again, applicant appears to be arguing limitations not claimed.

Applicant's arguments are not found persuasive.

6. This is an enablement rejection.

Claims 22-36 and 44-46 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antibodies and antigen-binding fragments thereof comprising one variable region from L chain, and one variable region from H chain, does not reasonably provide enablement for antibodies and antigen-binding fragments thereof variable regions both from a L chain, or a H chain. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's arguments, filed 12/12/05, have been fully considered, but is not deemed persuasive for reasons below.

Applicant's arguments and the examiner's rebuttal are essentially the same of record and as addressed herein.

Again, the applicant further argues, besides those above, that applicants teach how to generate, screen and identify antibodies capable of binding IL-18, and one of ordinary skill in the art can readily comprehend the structural features necessary to generate antibodies to IL-18.

Again, as pointed out previously, this argument has not been found persuasive because, besides the reasons addressed previously, above and herein.
It was not predictable that an antibody fragment comprising two variable regions of a L chain, or two variable regions of a H chain would have desired function. As such, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Again, applicant appears to be arguing limitations not claimed.

Applicant's arguments are not found persuasive.

Again, as pointed out previously, applicant is invited to consider amending the claims to recite language such as "comprising one variable region from L chain, and one variable region from H chain" to obviate this rejection, provided there is sufficient written description in the specification as filed.

Again, applicant appears to be arguing limitations not claimed.

Applicant's arguments are not found persuasive.

7. Claims 4-12, 14-24, 44-46 and 61 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kucherlapati et al. (US6,075,181, of record) and Dinarello et al. (J. Leukoc. Biol. 1998, 63:658-664. IDS #A4), for the reasons of record set forth in the previous Office Actions.

Applicant's arguments, in conjunction with basic legal principles of obviousness, filed 12/12/05, have been fully considered, but are not deemed persuasive for reasons below.

Again, applicant argues that Dinarello does not teach, suggest or motivate to generate fully human antibodies to IL-18, that Kucherlapati does not disclose IL-18, and does not teach, suggest or motivate to generate fully human antibodies to either IL-18, or specifically to human IL-18, that cited references, either singularly or in combination, do not teach, suggest or motivate the same, or method of making the same, and that the examiner fails to provide any evidence to support motivation to combine the cited art, and merely showing that all the elements of the claimed invention are known in the art is insufficient to establish obviousness.

Again, as pointed out previously, this argument has not been found persuasive for the following reasons.

Again, in response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, the teaching, suggestion, or motivation to make the claimed antibody can be readily found in the cited references as Dinarello teaches availability of human IL-18, the involvement of IL-18 in clinical pathology as that antibodies to IL-18 can inhibit the in vivo production of other pro-inflammatory cytokines, and that neutralizing anti-IL-I8 antibodies are a therapeutic option for specific blockade of IL-18.

Additionally, Kucherlapati teaches a method of producing fully human monoclonal antibodies to any protein of interest, but especially cytokines, and advantages of such antibodies in avoiding the undesired immune responses elicited by administering non-human antibodies to humans. Therefore, it is instantly obvious to a person having ordinary skill in the art to combine the teachings of the cited references and to make the human anti-IL-18 antibodies as claimed for the purpose of disease treatment using the method taught by Kucherlapati.

Again, applicant argues that without applicants disclosure, it is not obvious to make a leap from various therapeutic options as clinical strategy to block IL-18 to one specific cure, namely a human anti-IL-18 antibody, or to combine the teachings of the two references to arrive at applicants invention.

Again, this argument has not been found persuasive because none of the teachings, from which the instant rejection relies upon, is from applicants disclosure, instead they are all from the cited prior art references.

Again, applicant argues in conjunction with Cardiac Pacemakers Inc. v. St. Jude Medical, Inc. 381 F.3d 1371, 1377 (2004), that recognition of a need does not render obvious the achievement that meets that need, and there is an important distinction between the general motivation to cure an uncured disease and the motivation to create a particular cure, that none of the cited art singularly or in combination, provides any teaching, suggestion, or motivation to arrive at applicants invention, and that a disclosure of a method to generate human monoclonal antibodies, combined with a reference disclosing neutralizing anti-IL-18 antibodies is not a clear and particular teaching, suggestion, or motivation to make the fully human anti-IL-18 antibody of the present invention.

Again, this argument has not been persuasive for the following reasons. First, if either reference had explicitly taught the antibody as claimed, the present invention would have been rejected under 35 U.S.C. 102. Further, besides the reasons addressed above, the cited case law does not apply in the instant situation because in addition to the teachings of neutralizing anti-IL-18 antibodies, more importantly, Dinarello clearly teaches 1) the pathological role of IL-18 in disease development as that IL-18 is evolving as a major as a pro-inflammatory cytokine with implications for a role in inflammatory and infectious diseases, and it may also be a player in autoimmune diseases (page 658, the right column), and anti-IL-l8 antibodies suitable for treating human diseases, and 2) neutralizing anti-IL-l8 antibodies are a therapeutic option for specific blockade of IL-18. Furthermore, the prior art references teach disease treatment, and there is no such thing as the general motivation to cure an uncured disease in the references. Therefore, such argument is irrelevant. Furthermore, although Dinarello does not teach a human anti-IL-18 antibody or a method of making such, Kucherlapati teaches a method of producing fully human monoclonal antibodies to any protein of interest, but especially cytokines, and advantages of such antibodies. Therefore in contrast to applicant's assertions, the combined teachings provide strong teaching, suggestion, or motivation to arrive at applicants invention.

Again, applicant argues that the combination of the cited art is made by the examiner, upon guidance, direction, and motivation to do so, by applicant's present invention, and that this is hindsight reconstruction and is impermissible as a basis for 103 rejection.

Again, this argument has not been found persuasive for the reasons addressed above. In addition, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Also, the arguments of counsel cannot take the place of objective evidence in the record. In re Schulze, 145 USPQ 716, 718 (CCPA 1965). See MPEP 716.01(c).

Applicant's arguments are not found persuasive.

7. Claims 37 and 38 are allowable.

8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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